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IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF:

Tamotsu KONDOW, et al.

SERIAL NO.: 09/996,591

FILED: NOVEMBER 30, 2001

FOR: METHODS FOR DETERMINING NUCLEOTIDE SEQUENCES OF SINGLE
NUCLEIC ACID MOLECULES

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: GROUP ART UNIT: 1634

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: EXAMINER: LU

PRELIMINARY AMENDMENT AND RESPONSE TO RESTRICTION REQUIREMENT

ASSISTANT COMMISSIONER FOR PATENTS
WASHINGTON, D.C. 20231

SIR:

In response to the Official Action dated August 7, 2002, Applicants elect, with
traverse, Group I, Claims 1-11, for further prosecution. In addition, please amend the above
identified application as follows:

IN THE CLAIMS

Cancel Claims 12-22.

Please amend the claims as shown in the marked-up copy to read as follows:

-1. (Amended) A method for determining a nucleotide sequence of a nucleic acid by
single dye molecule detection, which comprises:

- (a) immobilizing a nucleic acid molecule, or a primer which has a sequence
complementary to a part of the sequence of the nucleic acid molecule, onto the
surface of a solid;

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- (b) annealing a primer, which has a sequence complementary to a part of the sequence of the nucleic acid molecule, or a nucleic acid molecule to the nucleic acid molecule or the primer, respectively;
 - (c) providing a solution which contains DNA polymerase and one type of dye-labeled dNTP, where N is A, T or U, G or C, or RNA polymerase and one type of dye-labeled NTP, where N is A, U, G or C, to said immobilized nucleic acid molecule, and allowing the nucleotide to react with the 3' end of said primer, whereby a nucleotide, which forms a base-pair with a base opposed to the reaction site, is bound to the primer by action of the polymerase;
 - (d) detecting a bound, dye-labeled dNTP or NTP;
 - (e) disrupting the dye molecule of the bound, dye-labeled dNTP or NTP;
 - (f) repeating (c) to (e) while changing the type of dye-labeled dNTP or NTP in turn, to sequentially bind dNTPs or NTPs which forms a base-pair with the nucleotides of the nucleic acid molecule; and
 - (g) determining a nucleotide sequence of the nucleic acid molecule based on the types of the sequentially bound dNTPs or NTPs.

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3. (Amended) The method of Claim 1, wherein (d) comprises optically detecting the dye molecule of said dye-labeled dNTP or NTP.

4. (Amended) The method of Claim 1, wherein (d) comprises exciting dye molecules by irradiation of a laser beam and detecting the thus released fluorescent signal.

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6. (Amended) The method of Claim 1, wherein said disruption of dye molecules in (e) is performed by irradiation of a laser beam stronger than that in (d).

BASIS FOR THE AMENDMENT

Claims 12-22 have been canceled.

Claims 1-4 and 6 have been amended.

The amendment of Claim 1 is supported by original Claims 1 and 11. The amendment of Claims 2-4 and 6 are supported by the corresponding original claims.

No new matter is believed to have been entered by the present amendments.

REMARKS

Claims 1-11 and 23-25 are pending in the present application.

The Office has required restriction in the present application as follows:

- Group I: Claims 1-11, drawn to a method for determining a nucleotide sequence of a nucleic acid by single dye molecule detection;
- Group II: Claims 12-22, drawn to a method for determining a nucleotide sequence of a nucleic acid by single dye molecule detection; and
- Group III: Claims 23-25, drawn to a kit.

Applicants have elected Group I, Claims 1-11, with traverse.

Restriction between Groups I and II is moot in view of the amendments presented herein.

In regard to Groups I and III, the Office has characterized the relationship between these two groups as product and process of use. Citing MPEP §806.05(h), the Office concludes that the product as claimed can be used in "PCR or RNA synthesis." However, the Office has not provided reasons and/or examples to support this conclusion. Further, the Office has failed to show that the proposed use of the claimed composition in "PCR or RNA synthesis." is materially different from the claimed use. Accordingly, Applicants respectfully submit that the Office has failed to meet the burden necessary in order to sustain the

Restriction Requirement. Withdrawal of the Restriction Requirement is respectfully requested.

MPEP §803 states as follows:

If the search and examination of an entire application can be made without serious burden, the Examiner must examine it on its merits, even though it includes claims to distinct or independent inventions.


Applicants submit that a search of all claims would not constitute a serious burden on the Office.

For the reasons set forth above, Applicants contend that the Restriction Requirement is improper and should be withdrawn.

Applicants respectfully submit that the above-identified application is now in condition for examination on the merits, and early notice of such action is earnestly solicited.

Respectfully submitted,

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